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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/714,348	11/14/2003	Suheir Assady	85189-5400	4072

28765 7590 10/20/2004

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EXAMINER	
LIETO, LOUIS D	

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 10/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/714,348	ASSADY ET AL.	
	Examiner	Art Unit	
	Louis D Lieto	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-33 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-33 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-19 drawn to a cell population comprising insulin-producing cells derived from human embryonic stem cells., classified in class 435, subclass 325.

II. Claims 20 and 23-25, drawn to a clone of non-differentiated human stem cells stably transfected with a vector comprising the DNA coding sequence of human insulin promoter, classified in class 435, subclass 325.

III. Claims 21 and 22 are drawn to a cell population comprising pluripotent precursors of beta islet cells of the pancreas derived from human embryonic stem cells, classified in class 435, subclass 325.

IV. Claim 26 and 27, drawn to a method for *in vitro* enrichment of insulin-producing cells derived from stem cells, classified in class 435, subclass 70.1.

V. Claim 28-33, drawn to a method of cell replacement therapy, the improvement of which comprises administering to a subject in need of such therapy insulin producing cells derived from human embryonic stem cells, classified in class 424, subclass 93.1.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are patentably distinct inventions for the following reasons. In the instant case the different invention of group I is to a cell population comprising insulin-

producing cells derived from human embryonic stem cells, while the invention of group II is to drawn to a clone of non-differentiated human stem cells stably transfected with a vector comprising the DNA coding sequence of human insulin promoter. The invention of group I is to a mixed population of cells with different stages of maturation that naturally produce insulin , while the invention of group II is to a uniform group of cells and a vector coding sequence of the human insulin promoter. The invention of group II requires a vector that is not necessary for group I. Further, the clone of group II can be produced without the cell population of group I. Neither invention requires the other.

Inventions I and III are patentably distinct inventions for the following reasons. In the instant case different invention of group I is to a cell population comprising insulin-producing cells derived from human embryonic stem cells, while the invention of group III is to drawn to a cell population comprising pluripotent precursors of beta islet cells of the pancreas derived from human embryonic stem cells. The inventions of group I and III can be used in materially different ways. The invention of group I is useful as a tissue graft or an *in vitro* source of insulin. The invention of group III is to a mixed population of cells that can form the beta islet cells of the pancreas.

Inventions I and IV are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the cell population of group I can be used as a tissue graft or an *in vitro* source of insulin. Further,

the invention of group IV can be made from adult or embryonic stem cells from any animal, while the invention of group I is derived from human embryonic stem cells.

Inventions I and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case cell population of group I can be used as an *in vitro* source of insulin in addition to the method of group V .Further, the cell population can be used for *in vitro* assays to study the molecular biology of insulin production.

Inventions II and III are patentably distinct inventions for the following reasons. In the instant case the different invention of group II is to a clone of non-differentiated human stem cells stably transfected with a vector comprising the DNA coding sequence of human insulin promoter, while the invention of group III is to drawn to a cell population comprising pluripotent precursors of beta islet cells of the pancreas derived from human embryonic stem cells. The invention of group II is to a uniform group of cells, while the invention of group III is to a mixed population of cells that can form the beta islet cells of the pancreas. The clone of group is non-differentiated and therefore lacks any characteristics of the cell population of group III. Further, the clone of group II can be produced without the cell population of group III. Neither invention requires the other.

Inventions II and IV, V are patentably distinct inventions for the following reasons. In the instant case the different invention of group II is to a clone of non-differentiated human stem cells stably transfected with a vector comprising the DNA coding sequence of human insulin

promoter, while the invention of groups IV and V are to methods of using insulin producing cells derived from stem cells. The invention of group II is to a uniform group of non-differentiated human stem cells, while the invention of group IV is to adult or embryonic stem cells from any animal. Further, the cells of groups IV and V are required to produce insulin, while the clone of group II is not. Additionally, the clone of group II can be produced without the cell population of group III. Neither invention requires the other.

Inventions III and IV, V are patentably distinct inventions for the following reasons. In the instant case the invention of group III is to drawn to a cell population comprising pluripotent precursors of beta islet cells of the pancreas derived from human embryonic stem cells, while the invention of groups IV and V are to methods of using insulin producing cells derived from stem cells. The invention of group III is to a mixed population of cells that can form the beta islet cells of the pancreas, while the invention of group IV is to adult or embryonic stem cells from any animal. Neither group IV or V require that the stem cells be transfected with the insulin promoter. Neither invention requires the other.

Inventions IV and IV are patentably distinct inventions for the following reasons. In the instant case the different invention of group IV is to a method for *in vitro* enrichment of insulin-producing cells derived from stem cells, while the invention of group V is drawn to a method of cell replacement therapy. The invention of group IV is to adult or embryonic stem cells from any animal, while the invention of group V is to cells derived from human embryonic stem cells. Further, the method of group IV is performed *in vitro*, while the invention of group V is performed *in vivo*. Neither invention requires the other.

Furthermore, searching the inventions of groups I-V together would impose a serious search burden. In the instant case, the search of the mixed cell population of differentiated cells of group I, the insulin promoter transfected single cell clone of group II, the beta islet cell precursor population of group III, the method of *in vitro* enrichment of an insulin producing cell population of group IV and the method of cell replacement therapy of group V are not coextensive. Each cell population comprises a separate area in the art, differentiated cells are substantially different from single cell clones and precursor cells. The methods are distinct from both the cells and from each other because one is practiced *in* vitro and the other *in* situ. As such, it would be burdensome to search the inventions of groups I-V together.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and different search requirements, restriction for examination purposes as indicated is proper.

This application contains claims directed to the following patentably distinct species of the claimed invention. The invention of group I lists the following patentably distinct species of genes expressed by the insulin producing cells:

a) insulin

b) islet glucokinase

c) Glut-2 glucose transporter

d) insulin promoter factor1/pancreatic and duodenal homeobox gene 1 IPF1/PDX1 transcription factor

e) NgN3 transcription factor

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-19 and 22 generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Lou Lieto whose telephone number is (571) 272-2932. The examiner can normally be reached on Monday-Friday, 9am-5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Amy J Nelson can be reached on (571) 272-0804. The fax phone number for the organization where this application or proceeding is assigned is (703)-872-9306. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available

through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Patent applicants with problems or questions regarding electronic images that can be viewed in the PAIR can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

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PRIMARY EXAMINER